
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

IXI QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended July 31, 2002

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 001-15167

BIOPURE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State of Incorporation)

04-2836871

(IRS Employer Identification Number)

11 Hurley Street, Cambridge, Massachusetts

(Address of principal executive offices)

02141

(Zip Code)

(617) 234-6500

(Registrant's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

The number of shares outstanding of each of the issuer's classes of common stock as of August 31, 2002 was:

Class A Common Stock, \$.01 par value	29,205,269
Class B Common Stock, \$1.00 par value	117.7

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Biopure®, Hemopure® and Oxyglobin® are registered trademarks of Biopure Corporation.

BIOPURE CORPORATION

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	July 31, 2002	October 31, 2001
Assets:		
Current assets:		
Cash and cash equivalents	\$ 30,182	\$ 36,089
Accounts receivable, net	139	724
Inventories, net	4,919	4,665
Other current assets	1,708	771
Total current assets	36,948	42,249
Property, plant and equipment, net	38,089	30,162
Other assets	11,674	11,776
Total assets	\$ 86,711	\$ 84,187
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	\$ 891	\$ 1,348
Accrued expenses	6,728	4,949
Total current liabilities	7,619	6,297
Long-term debt	9,762	5,205
Deferred compensation	184	1,792
Total long-term liabilities	9,946	6,997
Stockholders' equity:		
Preferred stock, \$0.01 par value, 30,000,000 shares authorized, no shares outstanding	—	—
Common stock:		
Class A, \$0.01 par value, 100,000,000 shares authorized, 29,205,269 shares outstanding at July 31, 2002 and 25,225,083 at October 31, 2001	292	252
Class B, \$1.00 par value, 179 shares authorized, 117.7 shares outstanding	—	—
Capital in excess of par value	415,395	383,570
Contributed capital	24,574	24,574
Notes receivable	(255)	(1,655)
Accumulated deficit	(370,860)	(335,848)
Total stockholders' equity	69,146	70,893
Total liabilities and stockholders' equity	\$ 86,711	\$ 84,187

Note: The balance sheet at October 31, 2001 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

See accompanying notes.

BIOPURE CORPORATION

Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	July 31, 2002	July 31, 2001	July 31, 2002	July 31, 2001
Revenues:				
Oxyglobin	\$ 259	\$ 945	\$ 1,915	\$ 2,513
Other	1	1	1	6
Total revenues	260	946	1,916	2,519
Cost of revenues	2,559	903	4,305	2,587
Gross profit (loss)	(2,299)	43	(2,389)	(68)
Operating expenses:				
Research and development	7,063	10,297	22,188	27,486
Sales and marketing	875	784	1,953	2,070
General and administrative	2,569	1,538	9,303	13,364
Total operating expenses	10,507	12,619	33,444	42,920
Loss from operations	(12,806)	(12,576)	(35,833)	(42,988)
Other income, net	210	654	821	2,960
Net loss	\$(12,596)	\$(11,922)	\$(35,012)	\$(40,028)
Per share data:				
Basic net loss per common share	\$ (0.43)	\$ (0.47)	\$ (1.30)	\$ (1.60)
Weighted-average shares used in computing basic net loss per common share	29,141	25,134	26,854	25,018

See accompanying notes.

BIOPURE CORPORATION

Condensed Consolidated Statements of Cash Flows

(In thousands)
(Unaudited)

	Nine Months Ended	
	July 31, 2002	July 31, 2001
Operating activities:		
Net loss	\$(35,012)	\$(40,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,231	2,955
Equity compensation	(76)	6,924
Deferred compensation	(54)	(11)
Accrued interest on stockholders' notes receivable	(1)	(71)
Acquired research and development information	—	1,511
Changes in assets and liabilities:		
Accounts receivable	585	(166)
Inventories	(254)	(2,029)
Other current assets	(937)	61
Accounts payable	(457)	(197)
Accrued expenses	1,779	1,448
Net cash used in operating activities	(31,196)	(29,603)
Investing activities:		
Purchases of property, plant and equipment	(6,340)	(2,254)
Escrow for new facility	—	(10,000)
Long term debt	(85)	—
Other assets	60	(63)
Net cash used in investing activities	(6,365)	(12,317)
Financing activities:		
Net proceeds from sale of common stock	31,766	(648)
Payment of notes receivable from stockholders	80	451
Amendment of note receivable from stockholder	(233)	—
Proceeds from exercise of options and warrants	41	1,689
Proceeds from exercise of non lapse restricted stock	—	132
Net cash provided by financing activities	31,654	1,624
Net decrease in cash and cash equivalents	(5,907)	(40,296)
Cash and cash equivalents at beginning of period	36,089	88,828
Cash and cash equivalents at end of period	\$ 30,182	\$ 48,532
Non-cash transactions:		
Land and license rights acquired upon conversion of stock option	\$ 139	\$ 1,005
New facility construction financed through capital lease (classified as long-term debt)	\$ 4,642	\$ 2,693
Settlement of deferred compensation and accrued interest	\$ (1,601)	\$ —
Settlement of note receivable and accrued interest	\$ 1,601	\$ —

See accompanying notes.

BIOPURE CORPORATION

Notes to Condensed Consolidated Financial Statements

July 31, 2002

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended July 31, 2002 are not necessarily indicative of the results that may be expected for the year ending October 31, 2002.

The Company has financed operations from inception primarily through sales of equity securities, development and license agreement payments, interest income and debt. The Company has not been profitable since inception and had an accumulated deficit of \$370,860,000 as of July 31, 2002. Management expects that the Company will continue to generate losses from operations for the next several years. The Company will explore opportunities to raise capital through sales of securities and potential joint venture or licensing agreements, or leasing arrangements.

At July 31, 2002, the Company had \$30,182,000 in cash and cash equivalents. Biopure raised \$31,766,000 through the sales of equity in the first nine months of fiscal 2002. Based on the Company's current operating plan, Biopure requires approximately \$13,000,000 for the last three months of fiscal 2002 to support applications to the European regulatory authorities for marketing approval of Hemopure, the ramp up of production of Hemopure and Oxyglobin at the expanded Cambridge manufacturing facility, the additional spending for the South Carolina manufacturing facility discussed below, market development for Hemopure in South Africa and sales of Oxyglobin.

The cash on hand on July 31, 2002 is expected to fund operations into the second quarter of fiscal 2003 or possibly into the third quarter, depending on the amount of Hemopure sales, if any, to South Africa.

Our cash requirements and our forecast of the period of time through which our financial resources would be adequate to support our operations may vary significantly from current projections and actual results may vary.

For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended October 31, 2001.

2. Net Loss per Share

Basic net loss per common share is computed based on the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed based upon the weighted-average number of common shares outstanding during the year, adjusted for the dilutive effect of shares issuable upon the conversion of convertible stock outstanding and the exercise of common stock options and warrants determined based upon the average market price of common stock for the period. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share are the same.

BIOPURE CORPORATION
Notes to Condensed Consolidated Financial Statements
July 31, 2002
(Unaudited)
(Continued)

3. Inventories

Inventories are valued at the lower of cost (determined using the first-in, first-out method) or market. Inventories were as follows:

	July 31, 2002	October 31, 2001
<i>In thousands</i>		
Raw materials	\$2,114	\$ 771
Work-in-process	781	243
Finished goods-Oxyglobin	913	1,886
Finished goods-Hemopure	1,111	1,765
	<u>\$4,919</u>	<u>\$4,665</u>

4. Accrued Expenses

Accrued expenses consisted of the following:

	July 31, 2002	October 31, 2001
<i>In thousands</i>		
Clinical trials	\$ 426	\$ 662
Preparation of biologic license application	1,089	306
Capacity upgrade	195	375
Accrued payroll and related employee expenses	1,130	1,365
Accrued vacation	562	398
Accrued legal expenses	435	257
South Carolina facility engineering & design	684	—
Insurance premiums	932	—
Other	1,275	1,586
	<u>\$6,728</u>	<u>\$4,949</u>

5. Commitment

In December 2001, Sumter Realty Group, LLC signed an amended letter of intent for the construction and financing of a new 500,000 unit Hemopure plant in South Carolina. The new plant is expected to cost approximately \$120,000,000 and is expected to be financed through a capital lease. As such, the financial statements include property, plant and equipment and offsetting debt. As of July 31, 2002, \$11,098,000 has been included in property, plant and equipment and \$9,762,000 in long term debt reflecting expenditures made by Biopure for the engineering and design costs of the facility. Of the \$11,098,000, \$10,000,000

BIOPURE CORPORATION
Notes to Condensed Consolidated Financial Statements
July 31, 2002
(Unaudited)
(Continued)

has been recorded as a deposit in long-term assets, as this amount is expected to be refunded upon receipt of approval of Hemopure by the United States Food and Drug Administration (FDA) and if a formal lease agreement has been executed. If FDA approval is not received or a lease is not signed, the \$10,000,000 deposit will not be returned to the Company and will be treated as a capital expenditure, and as a capital expenditure will be subject to an immediate impairment review pursuant to SFAS No. 121, "Accounting for Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" (and SFAS No. 144, applicable in fiscal 2003). A lease for the South Carolina facility has not yet been signed. Biopure anticipates investing an additional \$1,764,000 for detailed engineering work, including shop drawings for major equipment and steel fabrication. In addition Biopure is committed to pay a finder's fee, of approximately 2% of the net amount financed, to a consultant when financing for the South Carolina facility is completed.

6. Financing Activities

On May 9, 2002, the Company raised \$4,895,000 in net proceeds from the sale of 690,000 shares of its common stock in connection with the common stock shelf registration statement filed with the SEC in March, 2002. The Company issued 20,700 warrants to the placement agent for these shares with an exercise price of \$7.67 per share, resulting in an immaterial valuation.

Biopure is a party to a \$75,000,000 equity line stock purchase agreement with Société Générale. Under this agreement, Biopure has the option of drawing up to a balance (as of July 31, 2002) of \$67,750,000 until June 2003, subject to certain limitations, in exchange for the issuance of Biopure common stock. The primary limitation on use of the line is a minimum trading price for our common stock of \$13 per share. As of July 31, 2002, the Company had drawn \$7,250,000, all in fiscal 2002, under this agreement. The Company is currently unable to raise funds through this agreement because its recent stock prices have been below the minimum price specified in the agreement.

7. Transaction with Related Party

In August 1990, the Company awarded deferred compensation of \$700,000 to Carl Rausch, then Chairman and Chief Executive Officer. The deferred amount with interest was to be paid on July 31, 2003. The Company also made a loan of \$700,000 to Mr. Rausch in August 1990, the proceeds of which were used to purchase shares of the Company's class A common stock. On July 29, 2002, Mr. Rausch settled the interest accrued on his deferred compensation and the Company settled the interest due on the loan which were both \$901,000. Biopure accelerated the deferred compensation payment of \$700,000 to Mr. Rausch, of which \$233,100 was withheld for taxes and the balance of \$466,900 was paid on the loan, leaving a principal loan balance of \$233,100. This remaining loan balance bears interest at prime rate (4.75% at July 31, 2002) and is included in stockholders' equity as notes receivable in the accompanying consolidated financial statements. Interest payments are made on a current basis and the principal on the loan is due on July 31, 2007.

8. Litigation

Biopure and its former Chairman and Chief Executive Officer were named as defendants in a purported class action (resulting from the consolidation of five actions, the first of which was filed on February 5, 2002) in the U.S. District Court for the District of Massachusetts (the "Court") by alleged purchasers of Biopure's common stock and subsequently amended (the "complaints"). The complaints claimed that Biopure violated the federal securities laws by publicly disseminating materially false and misleading statements regarding the anticipated time of a biologic license application Biopure expected to make to the U.S. Food and Drug Administration (the "FDA") and that Biopure failed to disclose materially adverse information regarding the data Biopure gathered in the Phase III clinical trials in support of its FDA application, resulting in the artificial inflation of Biopure's common stock price during the purported class period of May 8, 2001 through March 21, 2002. By Memorandum And Order dated September 4, 2002, the Court granted defendants' motion to dismiss in its entirety, dismissing all of plaintiffs' claims with prejudice. The deadline to appeal is October 7, 2002.

BIOPURE CORPORATION

Independent Accountants' Review Report

The Board of Directors
Biopure Corporation

We have reviewed the accompanying condensed consolidated balance sheet of Biopure Corporation (the Company) as of July 31, 2002, and the related condensed consolidated statements of operations for the three-month and nine-month periods ended July 31, 2002 and 2001, and the condensed consolidated statements of cash flows for the nine-month periods ended July 31, 2002 and 2001. These financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data, and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States, which will be performed for the full year with the objective of expressing an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to the accompanying condensed consolidated financial statements referred to above for them to be in conformity with accounting principles generally accepted in the United States.

We have previously audited, in accordance with auditing standards generally accepted in the United States, the consolidated balance sheet of the Company as of October 31, 2001, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended (not presented herein) and in our report dated December 10, 2001 (except for Note 14, as to which the date is January 22, 2002), we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of October 31, 2001, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Ernst & Young LLP

Boston, Massachusetts
September 10, 2002

BIOPURE CORPORATION

**Management's Discussion and Analysis of
Financial Condition and Results of Operations
July 31, 2002**

Cautionary Statement Regarding Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included elsewhere in this report. Except for strictly historical information contained herein, matters discussed in this report constitute forward-looking statements. When used herein, the words "expects," "estimates," "intends," "plans," "should," "anticipates" and similar expressions are intended to identify such forward-looking statements. Actual results could differ materially from those set forth in the forward-looking statements. There can be no assurance that Biopure will be able to commercially develop its oxygen therapeutic products, that necessary regulatory approvals will be obtained, that anticipated milestones will be met in the expected timetable, that any clinical trials will be successful, or that any approved product will attain market acceptance and be sold in the quantities anticipated. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the Company's operations and business environment. These risks include, without limitation, the Company's stage of product development, history of operating losses, accumulating deficits, and uncertainties and possible delays related to clinical trials, regulatory approvals, possible healthcare reform, manufacturing capacity, market acceptance, competition and the availability of sufficient financing to support operations. In light of the substantial risks and uncertainties inherent in all future projections, the inclusion of forward-looking statements in this report should not be regarded as representations by the Company that the objectives or plans of the Company will be achieved. The Company undertakes no obligation to release publicly the results of revisions to these forward-looking statements to reflect events or circumstances after the date hereof. Reference is made in particular to the risk factors set forth in Exhibit 99.1 to this report and the discussions set forth below in this report under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Overview

We are a leading developer, manufacturer and supplier of a new class of pharmaceuticals, called oxygen therapeutics. Our oxygen therapeutics are administered intravenously into the circulatory system to increase oxygen transport to the body's tissues. We have developed and manufacture, using a proprietary process and patented technology, two hemoglobin-based oxygen carriers, Hemopure and Oxyglobin. Two Phase III clinical trials have been completed for Hemopure, which are a major component of our application submitted to the FDA on July 31, 2002 for marketing approval in the United States. The FDA has 60 business days from the submission of a biologic license application (BLA) to determine the application's acceptability for review, and it generally determines the approvability of an accepted application within 12 to 16 months of the submission date. In fiscal 2001, Hemopure was approved in South Africa for the treatment of adult surgical patients who are acutely anemic and for the purpose of eliminating, delaying or reducing the need for allogenic red blood cells in these patients. Oxyglobin, for veterinary use, is the only hemoglobin-based oxygen carrier approved by the FDA and the European Medicines Evaluation Agency.

Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financings, strategic alliances and interest income. We have not been profitable since inception and had an accumulated deficit of \$370,860,000 as of July 31, 2002. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure in Europe and other markets and pre-marketing expenditures for Hemopure. We began generating revenue from the sale of Oxyglobin in fiscal 1998.

BIOPURE CORPORATION
Management's Discussion and Analysis of
Financial Condition and Results of Operations
July 31, 2002
(continued)

We believe our cash and cash equivalents, as of July 31, 2002, are sufficient to fund our current plan into the second quarter of fiscal 2003 or possibly into the third quarter depending on the amount of Hemopure sales, if any, to South Africa. Under this plan, our operations for the balance of fiscal 2002 will be in support of our applications to the European regulatory authorities for marketing approval of Hemopure, the ramp up of production of Hemopure and Oxyglobin at our upgraded Cambridge, Massachusetts manufacturing facility, market development for Hemopure in South Africa and the sales of Oxyglobin. Expenditures, including additional personnel and other costs for research and clinical development of additional indications for Hemopure and most expenditures in preparation for marketing and sales of Hemopure in the United States, will be deferred until sufficient funds, in addition to those on hand, are available.

Critical Accounting Policies

SFAS 121 (and SFAS 144, applicable in fiscal 2003) require that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Our investments in property and equipment, including construction in progress and the new facility construction; real property license rights related to the source of supply of our major raw material and a production process; and the asset related to the initial new facility project costs are the principal long-lived assets that could be subject to such a review. The events or changes in circumstances, among others, that may result in an impairment of these assets are a significant delay in expected regulatory approvals for our human product, a change in the source of supply of the major raw material, the inability to obtain a lease for the South Carolina facility, or lack of adequate demand for our products.

Results of Operations

Three months ended July 31, 2002 compared to three months ended July 31, 2001

Total revenues were \$260,000 for the third quarter of fiscal 2002 compared to \$946,000 for the corresponding period in fiscal 2001. This decrease in veterinary sales of Oxyglobin® is due to low inventory resulting from expansion and revalidation of Biopure's manufacturing facilities. The Company is allocating the limited product produced before the expansion to its largest customers, and is accumulating back orders, which totaled approximately 5,900 units at August 31, 2002. Biopure expects to fill back orders during the first quarter of fiscal 2003 following anticipated regulatory clearance to ship product manufactured at the revalidated facilities.

Cost of revenues increased to \$2,559,000 for the third quarter of fiscal 2002 compared to \$903,000 for the corresponding period last year. When manufacturing resumed in late May 2002, the allocation of unabsorbed costs to research and development ended and all costs were charged to cost of revenues or inventory. Cost of revenues for the third quarter of fiscal 2002 reflects manufacturing inefficiencies during ramp-up of the expanded facilities; manufacturing costs incurred during the ramp-up that exceeded selling price were charged to cost of revenues and not to inventory.

BIOPURE CORPORATION
Management's Discussion and Analysis of
Financial Condition and Results of Operations
July 31, 2002
(continued)

Research and development expenses include product and process development and engineering, pre-clinical studies, clinical trials, clinical trial materials and an allocation of unabsorbed fixed costs of manufacturing. Our research and development efforts have been focused on developing and gaining regulatory approval of Hemopure, our product for use in humans. The development and approval of Oxyglobin, our veterinary product, was a result of the development of Hemopure. Hemopure is approved for use in South Africa. During the third quarter of fiscal 2002, research and development efforts consisted primarily of the preparation of our BLA for Hemopure, which was filed with the FDA on July 31, 2002. Failure to gain one or more additional regulatory approvals during the next several years would make it difficult for the Company to continue its development efforts.

Research and development expenses decreased 31.4% to \$7,063,000 for the third quarter of fiscal 2002, compared to the third quarter of fiscal 2001. This decrease is due to a one-time expense of \$1,604,000 in the third quarter of fiscal 2001, of which \$1,511,000 was non-cash, related to the acquisition of Reperfusion Systems, Inc., a \$2,135,000 reduction in expenses for activities associated with data organization and analyses for the Phase III orthopedic surgery trial of Hemopure®, a \$784,000 reduction in expenses for pre-clinical studies, and a \$782,000 reduction in the allocation of unabsorbed fixed manufacturing costs, as these costs are now charged to cost of revenues or inventory. The decrease in expenses was partially offset by an increase of approximately \$2,069,000 for preparing the BLA for Hemopure that was submitted to the FDA on July 31, 2002.

Sales and marketing expenses increased 11.6% to \$875,000 for the third quarter of fiscal 2002. Oxyglobin sales and marketing related expenses decreased 41.7% to \$457,000 for the third quarter of fiscal 2002 in line with the decrease in sales volume. This decrease is due primarily to reductions in veterinary educational programs. Market development expenses for Hemopure were classified as general and administrative expenses in previous quarters. Hemopure marketing expenses of \$418,000 are included in sales and marketing expenses for the third quarter of fiscal 2002 since Hemopure is being produced for sale to South Africa.

General and administrative expenses increased 67.0% to \$2,569,000 for the third quarter of fiscal 2002 compared to the same period in 2001. This increase is due to increased consulting expenses and the absence in 2002 of a \$793,000 credit realized in 2001 for non-cash compensation for stock options and warrants previously issued to non-employees; the 2001 credit was largely for stock options and warrants that fully vested in fiscal 2001 and require no further adjustments. The increase in expenses was partially offset by a decrease in market development expenses for Hemopure.

Other income was \$210,000 in the third quarter of fiscal 2002, compared to \$654,000 in the third quarter of fiscal 2001. This decrease reflects the Company's reduced cash balance and lower interest rates.

Nine months ended July 31, 2002 compared to nine months ended July 31, 2001

Total revenues, consisting entirely of Oxyglobin sales, decreased 23.9% to \$1,916,000 for the first nine months of fiscal 2002, compared with the corresponding period in 2001. Oxyglobin sales in Europe were \$200,000 for the first nine months of fiscal 2002 compared to \$104,000 in fiscal 2001. Oxyglobin was first sold into Europe in April of 2001. The decrease in domestic sales is due to low inventory resulting from expansion and revalidation of Biopure's manufacturing facilities. The Company is allocating its limited inventory of product produced before the expansion to its largest customers, and expects to fill backorders during the first quarter of fiscal 2003 following anticipated regulatory clearance to ship product manufactured at the revalidated facilities.

BIOPURE CORPORATION
Management's Discussion and Analysis of
Financial Condition and Results of Operations
July 31, 2002
(continued)

Cost of revenues was \$4,305,000 for first nine months of fiscal 2002 compared to \$2,587,000 for the corresponding period last year. When manufacturing resumed in late May 2002, the allocation of unabsorbed costs to research and development ended and all costs were charged to cost of revenues or inventory. Cost of revenues for the third quarter of fiscal 2002 reflects manufacturing inefficiencies during ramp-up of the expanded facilities; manufacturing costs incurred during the ramp-up that exceeded selling price were charged to cost of revenues and not to inventory. The allocations in May between cost of revenues and research and development were based on current and expected production levels and annual production capacities and required the judgment of Biopure's management.

Research and development expenses decreased 19.3% to \$22,188,000 for the first nine months of fiscal 2002 compared to the corresponding period last year. The decrease is due to a \$6,063,000 reduction in expenses for the U.S. Phase III clinical trial of Hemopure and a one-time expense of \$1,604,000 in 2001, of which \$1,511,000 was non-cash, related to the acquisition of Reperfusion Systems, Inc. In the first nine months of fiscal 2002, expenses for other clinical trials and pre-clinical work for additional Hemopure applications also decreased by \$1,435,000. This decrease in spending was partially offset by increased expenses of \$3,386,000 in preparation of the BLA, filed with the FDA on July 31, 2002 and the allocation of unabsorbed fixed manufacturing costs of \$421,000, incurred prior to June during the Cambridge facility expansion, allocated to research and development.

Sales and marketing expenses decreased 5.7% to \$1,953,000 for the first nine months of fiscal 2002. Oxyglobin sales and marketing related expenses decreased 25.8% to \$1,535,000 for the third quarter of fiscal 2002 in line with the decrease in sales volume. This decrease is primarily due to reductions in veterinary educational programs. Market development expenses for Hemopure were classified as general and administrative expenses for the first and second quarters. Hemopure marketing expenses of \$418,000 are included in sales and marketing expenses for the third quarter of fiscal 2002 since Hemopure is being produced for sale to South Africa.

General and administrative expenses were \$9,303,000 for the first nine months of fiscal 2002, a reduction of 30.4% compared to the same period last year. This decrease is due largely to non-cash charges for stock options and warrants issued to non-employees that vested fully in fiscal 2001 and require no further adjustments. The first nine months of fiscal 2001 included an expense of \$6,924,000 compared to a credit of \$77,000 for the corresponding period in fiscal 2002. Before the non-cash compensation charges, expenses for the first nine months of fiscal 2002 increased by \$2,940,000 primarily due to an expense of \$1,252,000 for product shipped to South Africa for use in a pre-launch medical education program, and increased information technology and consulting expenses compared to last year.

Other income was \$821,000 in the first nine months of fiscal 2002, compared to \$2,960,000 in the first nine months of fiscal 2001. This decrease reflects the Company's reduced cash balance and lower interest rates. Included in other income for the first nine months of 2002 is \$238,000 received as a contingent payment for a 1998 intellectual property transfer not related to Hemopure or Oxyglobin.

Liquidity and Capital Resources

At July 31, 2002, we had \$30,182,000 in cash and cash equivalents. We have raised \$31,766,000 through the sales of equity in the first nine months of fiscal 2002. Based on our current operating plan, we require approximately \$13,000,000 for the last three months of fiscal 2002 to support our applications to European regulatory authorities for marketing approval of Hemopure, the ramp up of production of Hemopure and Oxyglobin at our expanded Cambridge manufacturing facility, the additional spending for the South Carolina manufacturing facility discussed below, market development for Hemopure in South Africa and sales of Oxyglobin.

BIOPURE CORPORATION
Management's Discussion and Analysis of
Financial Condition and Results of Operations
July 31, 2002
(continued)

The cash on hand on July 31, 2002 is expected to fund operations into the second quarter of fiscal 2003 or possibly into the third quarter, depending on the amount of Hemopure sales, if any, to South Africa.

Expenditures, including additional personnel and other costs for research and clinical development of additional indications for Hemopure and most expenditures in preparation for marketing and sales of Hemopure in the United States, will be deferred until sufficient funds, in addition to those on hand, are available. Should management's plans not develop as anticipated, the Company will restrict certain of its planned activities and operations, as necessary, to sustain operations and conserve cash resources. Our cash requirements and our forecast of the period of time through which our financial resources would be adequate to support our operations may vary significantly from current projections and actual results may vary.

In December 2001, the Company signed an amended letter of intent for the construction and financing of a 500,000 unit Hemopure plant in South Carolina expected to cost \$120,000,000. During fiscal 2001, we paid \$10,000,000, Biopure's contribution to the cost of the facility, into an escrow account to fund certain initial expenditures related to the construction of the new facility. Under the proposed agreement for the construction and financing of the new plant, the \$10,000,000 in project cost funded by Biopure is expected to be refunded upon receipt of FDA approval for Hemopure and if a formal lease agreement has been executed. The \$10,000,000 has been accounted for as a deposit in long-term assets. If FDA approval is not received, the \$10,000,000 deposit will not be returned to the Company and will be treated as a capital expenditure, and as a capital expenditure will be subject to immediate impairment review pursuant to SFAS No. 121 (and SFAS No. 144, when applicable). As of July 31, 2002, \$11,098,000 has been included in property, plant and equipment and \$9,762,000 in long term debt reflecting expenses to date for the engineering and design costs of the planned manufacturing facility in Sumter, S.C. As of July 31, 2002, the Company had spent an additional \$1,336,000 for detailed engineering work, including shop drawings for major equipment and steel fabrication, to maintain the timeline for a validated, FDA-approved plant and profitability in fiscal 2005. Biopure anticipates investing an additional \$1,764,000 on these items. In addition Biopure will have to pay a finder's fee, of approximately 2% of the net amount financed, to a consultant when financing for the South Carolina facility is completed. Sumter Realty Group, LLC has recently accepted a letter of commitment from a potential investor for the full \$120,000,000 required to finance construction of a new manufacturing facility in South Carolina, which is designed to produce 500,000 Hemopure units per year. Certain due diligence activities are being conducted and draft documents are being prepared. If the final proposal is acceptable, closing could occur in November 2002.

Biopure is a party to a \$75,000,000 equity line stock purchase agreement with Societe Generale. Under this agreement, Biopure would have the option of drawing up to a remaining balance of \$67,750,000 until June 2003, if conditions under the agreement were met, in exchange for the issuance of Biopure common stock. As of August 31, 2002, the Company had drawn \$7,250,000, all in fiscal 2002, under this agreement. The Company is currently unable to raise funds through this agreement because its recent stock prices have been below the minimum price of \$13 per share specified in the agreement.

We plan to spend approximately \$1,000,000 in the balance of fiscal 2002 and approximately \$2,500,000 in fiscal 2003 on capital projects for our existing facilities. These fiscal 2002 planned expenditures are included in the cash requirements for the remainder of fiscal 2002 identified above.

We expect to continue financing our operations, until we are profitable, through sales of securities and joint venture, leasing or licensing arrangements. On March 11, 2002, we filed a \$30,000,000 common stock shelf registration statement with the SEC to facilitate future financings. On April 23, 2002, the Company raised net proceeds of \$19,689,000 from an offering of these registered

BIOPURE CORPORATION
Management's Discussion and Analysis of
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(continued)

shares. We realized an additional \$4,895,000 in net proceeds from another offering of these registered shares on May 9, 2002. The Company may sell additional shares under this shelf registration. We will also explore licensing and partnering arrangements where appropriate. We have not been profitable since inception and had an accumulated deficit of \$370,860,000 as of July 31, 2002. We will continue to generate losses for the next several years.

As of October 31, 2001, we had net operating loss carryforwards of approximately \$195,100,000 to offset future federal and state taxable income through 2021. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in our financial statements as of July 31, 2002. Utilization of such losses in future years may be limited under the change of stock ownership rules of the Internal Revenue Service.

BIOPURE CORPORATION
Part II— Other Information
July 31, 2002

Item 1. Legal Proceedings

As described in Item 3, Legal Proceedings, in the Company's Annual Report on Form 10-K for the year ended October 31, 2001, in 1995 the Opposition Division of the European Patent Office, revoked a process patent that had been granted to the Company. In response, the Company narrowed the patent claims and appealed the decision of the Opposition Division. The patent was reinstated during the appeal. On July 16, 2002, the patent was maintained in a decision in favor of Biopure.

Biopure and its former Chairman and Chief Executive Officer were named as defendants in a purported class action (resulting from the consolidation of five actions, the first of which was filed on February 5, 2002) in the U.S. District Court for the District of Massachusetts (the "Court") by alleged purchasers of Biopure's common stock and subsequently amended (the "complaints"). The complaints claimed that Biopure violated the federal securities laws by publicly disseminating materially false and misleading statements regarding the anticipated time of a biologic license application Biopure expected to make to the U.S. Food and Drug Administration (the "FDA") and that Biopure failed to disclose materially adverse information regarding the data Biopure gathered in the Phase III clinical trials in support of its FDA application, resulting in the artificial inflation of Biopure's common stock price during the purported class period of May 8, 2001 through March 21, 2002. By Memorandum And Order dated September 4, 2002, the Court granted defendants' motion to dismiss in its entirety, dismissing all of plaintiffs' claims with prejudice. The deadline to appeal is October 7, 2002.

Item 2. Changes in Securities and Use of Proceeds

On May 9, 2002 the Company issued warrants to purchase 20,700 shares of class A common stock to DP Securities, Inc. The warrants were issued in consideration of services rendered in the public sale by the Company of 690,000 shares of class A common stock. The warrants are exercisable for three years beginning on the first anniversary of their issuance. The Company relied on the exemption from registration in Section 4(2) of the Securities Act of 1933 (the "Act").

On June 25, 2002 the Company issued an option to Thomas A. Moore to purchase up to 300,000 shares of class A common stock. Neither the option nor the underlying shares were registered under the Act. The Company relied on the exemption from registration in Section 4(2) of the Act.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

- 10.1 Employment Agreement dated as of June 25, 2002, between the Company and Thomas A. Moore
- 10.2 Option dated as of June 25, 2002, in favor of Thomas A. Moore
- 10.3 Employment Agreement dated as of July 29, 2002, between the Company and Carl W. Rausch
- 10.4 Promissory note dated July 29, 2002 from Carl W. Rausch
- 10.5 Deferred Compensation Agreement dated July 29, 2002 between the Company and Carl W. Rausch
- 10.6 Agreement re Loan dated July 29, 2002 between the Company and Carl W. Rausch
- 10.7 Agreement dated June 25, 2002, between the Company and Paul A. Looney
- 15 Acknowledgement Letter of Ernst & Young LLP
- 99.1 Risk Factors
- 99.2 Certification of Thomas A. Moore pursuant to 18 U.S.C. Section 1350

99.3 Certification of Francis H. Murphy pursuant to 18 U.S.C Section 1350

- (b) A report on Form 8-K was filed on June 26, 2002, reporting elections of a Chairman of the Board and a President and Chief Executive Officer

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOPURE CORPORATION

Date: September 16, 2002

By: /s/ Francis H. Murphy

Francis H. Murphy
Duly authorized officer of the Registrant and
Chief Financial Officer

CERTIFICATIONS

I, Thomas A. Moore, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biopure Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

Date: September 13, 2002

/s/ Thomas A. Moore

Thomas A. Moore
Chief Executive Officer

CERTIFICATIONS

I, Francis H. Murphy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biopure Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

Date: September 13, 2002

/s/ Francis H. Murphy

Francis H. Murphy
Chief Financial Officer

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